

Food and Drug Administration, HHS

§ 522.1862

paragraph (a)(2) as in paragraph (c) of this section.

(3) Nos. 054628 and 058005 for use of product described in paragraph (a)(2) as in paragraph (c)(2) of this section.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. Administer by intravenous injection 10 mg per pound of body weight daily in three divided doses, not to exceed 800 mg daily regardless of weight. Limit intravenous administration to 2 successive days. Oral medication may follow.

(ii) *Indications for use*. It is used for the relief of inflammatory conditions associated with the musculoskeletal system.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Horses*—(i) *Amount*. Administer by intravenous injection 1 to 2 grams (g) per 1,000 pounds of body weight daily in three divided doses, not to exceed 4 g daily. Limit intravenous administration to not more than 5 successive days.

(ii) *Indications for use*. For the relief of inflammatory conditions associated with the musculoskeletal system.

(iii) *Limitations*. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16193, Mar. 25, 2014]

§ 522.1820 Pituitary luteinizing hormone powder for injection.

(a) *Specifications*. The drug is a lyophilized pituitary extract. Each 6-milliliter vial contains an amount equivalent to 25 milligrams of standard pituitary luteinizing hormone and is reconstituted for use by addition of 5 milliliters of 0.9 percent aqueous sodium chloride solution.

(b) *Sponsor*. No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. Cattle and horses: 25 milligrams; swine: 5 milligrams; sheep: 2.5 milligrams; and dogs: 1.0 milligram. Preferably given by intravenous injection, it may be administered subcutaneously. Treatment may be repeated in 1 to 4 weeks, or as indicated.

(2) *Indications for use*. As an aid in the treatment of breeding disorders related

to pituitary hypofunction in cattle, horses, swine, sheep, and dogs.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 52 FR 7832, Mar. 13, 1987; 79 FR 16193, Mar. 25, 2014]

§ 522.1850 Polysulfated glycosaminoglycan.

(a) *Specifications*. (1) Each 1-milliliter (mL) ampule of solution contains 250 milligrams (mg) polysulfated glycosaminoglycan.

(2) Each mL of solution packaged in 5-mL ampules or 20-, 30-, or 50-mL vials contains 100 mg polysulfated glycosaminoglycan.

(b) *Sponsor*. See No. 010797 in § 510.600(c) of this chapter.

(c) *Special considerations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Horses*—(i) *Indications for use*. For the treatment of noninfectious degenerative and/or traumatic joint dysfunction and associated lameness of the carpal and hock joints in horses.

(ii) *Amount*—(A) *Intra-articular use (carpal)*: 250 mg once a week for 5 weeks.

(B) *Intramuscular use (carpal and hock)*: 500 mg every 4 days for 28 days.

(iii) *Limitations*. Do not use in horses intended for human consumption.

(2) *Dogs*—(i) *Indications for use*. For control of signs associated with noninfectious degenerative and/or traumatic arthritis of canine synovial joints.

(ii) *Amount*. 2 mg per pound of body weight by intramuscular injection twice weekly for up to 4 weeks (maximum of 8 injections).

[72 FR 56896, Oct. 5, 2007, as amended at 74 FR 67816, Dec. 21, 2009]

§ 522.1862 Pralidoxime powder for injection.

(a) *Specifications*. Each vial contains 1 gram (g) of pralidoxime chloride powder for mixing with 20 cubic centimeters of sterile water for injection. Each milliliter of constituted solution contains 50 milligrams (mg) pralidoxime chloride.